

REMARKS

Applicant respectfully requests favorable reconsideration of this application light of the following remarks.

By this Amendment, Applicant amends claims 40. The Amendment to claim 40 finds non-limiting support at least in Fig. 2, original claims 1 and 11, and pp. 2-4 of the originally-filed application. In addition, Applicant amends claim 41 to place it in independent form. No new matter has been added.

On page 2 of the final Office Action, claims 40-52 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,211,638 to Dudar et al. (hereinafter "Dudar") in view of U.S. Patent No. 3,977,555 to Larson (hereinafter "Larson"). Applicant respectfully traverses the rejections.

No combination of Dudar and Larson discloses or suggests the present claims. For example, as-amended independent claim 40 recites a plastic fluid transfer device comprising, among other aspects,

a piercing mandrel formed integrally with and extending from the lid portion, the piercing mandrel including a piercing portion configured to pierce completely through a thickness of the elastic stopper[,] ... the piercing portion including a pointed end and a cylindrical portion of constant diameter, the piercing mandrel further including a conical sealing portion adjoining the cylindrical portion, the conical sealing portion having a diameter that continuously increases from the cylindrical portion to a position proximate the lid portion, the conical sealing portion being configured to seal a tear in the elastic stopper formed upon eccentric application of the fluid transfer device to the elastic stopper.

No combination of Dudar and Larson discloses at least this aspect of the claims alone or in combination with other aspects of the claims.

Dudar discloses a vial adapter configured to be coupled to a standard vial. In one embodiment, Dudar teaches that vial adaptor 736 has a hole 750 centered in a top member 740, which is aligned with a fluid flow member 738. Dudar further teaches that an adapter spike 752 is contiguous with the hole and “has a generally cylindrical, hollow body portion 754 which tapers into a solid center point 756.” See col. 12, lines 15-58 of Dudar. Dudar does not disclose or suggest that adapter spike 752 includes “a conical sealing portion adjoining the cylindrical portion, the conical sealing portion having a diameter that continuously increases from the cylindrical portion to a position proximate the lid portion,” as recited in as-amended claim 40. Indeed, the final Office Action concedes that Dudar fails to “teach a conical sealing portion proximal of the piercing portion for sealing tears in the elastic stopper of the vial.” See page 3 of the final Office Action.

Larson teaches a unit dose vial 10 with a safety cap 22 having a cap portion 24 and a needle structure 34. The needle structure 34 includes “a generally cylindrical body 36 provided with a small diameter downwardly tapering lower end extension 38 which is sharpened at its lower end as at 40.” See col. 3, lines 16-20 of Larson. As shown in Fig. 4, Larson discloses that needle structure 34 includes an enlargement 66 proximal lower end extension 38.

In formulating the rejection, the final Office Action asserts that enlargement 66 corresponds to the claimed sealing portion and alleges that enlargement 66 is substantially conical. See page 3 of the final Office Action. Although Applicant does not agree with the Office’s assertions and characterizations, Applicant has amended independent claim 40 to clarify that the claimed conical sealing portion “ha[s] a diameter

that continuously increases from the cylindrical portion to a position proximate the lid portion.” Larson fails to disclose or suggest that the portion of needle structure 34 adjoining lower extension 34 “ha[s] a diameter that continuously increases,” as required by claim 40. Instead, Larson explicitly states that the enlargement 66 has a “bulbuous outer surface.” See col. 4, lines 40 of Larson. That is, in contrast to claim 40, which requires “a diameter that continuously increases,” Larson teaches that enlargement 66 and lower extension 38 form a stepped configuration.

Accordingly, for at least this reason, independent claim 40 is allowable. Applicant requests reconsideration and withdrawal of the Section 103(a) rejection of independent claim 40 based on Dudar and Larson.

Applicant further submits that claims 42-52 depend either directly or indirectly from independent claim 40, and are therefore allowable for at least the same reasons that independent claim 40 is allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited references, and therefore at least some also are separately patentable.

By this Amendment, Applicant has placed claim 41 in independent form. Claim 41 recites a plastic fluid transfer device comprising, among other aspects, a piercing mandrel “including a conical sealing portion adjoining the cylindrical portion and widening to the lid portion . . . wherein the sealing portion of the piercing mandrel is configured to penetrate the elastic stopper when the bead is substantially disposed in the space.” No combination of Dudar and Larson teaches at least this aspect of claim 41.

As conceded on page 3 of the final Office Action, Dudar fails to disclose or suggest “a conical sealing portion adjoining the cylindrical portion and widening to the lid portion.” Larson fails to cure the deficiencies of Dudar. As discussed above, Larson disclose a needle structure 34 having an extension 38 and an enlargement 66 proximate to extension 38. Larson teaches that enlargement 66 has a “bulbuous outer surface” which “engages the central portion 18 of the seal 14 in order to limit penetration of the needle defining extension 38 through the seal 14.” See col. 4, lines 41-43 of Larson. That is, in contrast to claim 41 which requires that the sealing portion configured to “penetrate the elastic stopper,” Larson teaches that enlargement 66 abuts against seal 14 and depresses seal 14 when the bead is substantially received by cap portion 24. Thus, Larson fails to disclose or suggest at least the feature of a “sealing portion of the piercing mandrel configured to penetrate the elastic stopper when the bead is substantially disposed in the space,” as recited in new independent claim 41.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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